JUN 2 2 2001

HydroCision
100 Burtt Rd. Suite G01
Andover, MA 01810
Tel: 978-474-9300
Fax: 978-474- 5037

K011612

510K Summary of Safety and Effectiveness
Modification to the
HydroCision, Inc. Debridement System

1. Sponsor Name

   HydroCision, Inc
   100 Burtt Rd. Suite G01
   Andover, MA 01810
   Tel: 978-474-9300
   Contact Individual: Debbie Iampietro

2. Device Name

   Proprietary Name: HydroCision DebridementSystem
   Common/Usual Name: Pulse lavage with sharp debridement
   Classification Name: Unclassified Class II – General Surgery Devices

3. Identification of Legally Marketed Device

   The modified HydroCision, Inc Debridement System is substantially equivalent in intended use to the HydroCision, Inc Debridement System (K991383).

4. Device Description

   The HydroCision Debridement System uses a pressurized stream of sterile saline to lavage and clean wounds. The stream of saline simultaneously washes the tissue surface and vacuums away foreign material, including contamination and infected and necrotic tissue from the wound. The system employs two basic system components to achieve this purpose:

   - the reusable power console unit
   - the sterile, disposable pump cartridge, handpiece and tubing assembly

5. Intended Use

The HydroCision, Inc. Debridement System is intended for wound debridement, soft tissue debridement, and cleansing of the surgical site in applications in which, in the physicians judgement, would require the use of a pulse lavage device with sharp debridement. This device is not intended to be used on burns.

6 Comparison of Technological Characteristics

The modified HydroCision, Inc Debridement System is substantially equivalent in intended use and design to the currently marketed HydroCision, Inc Debridement System (K991383). This device is intended for wound debridement, soft tissue debridement, and cleansing of the surgical site. The device helps to remove blood, tissue debris and foreign matter from the operative or wound site.

The devices have similar flow rates and power requirements. The components of each system are similar in that they each contain: a reusable power console unit, a sterile, disposable pump cartridge, a handpiece assembly, and a tubing set. The only difference between the two devices is in the maximum pressure and the tip configuration. These differences do not raise new questions of safety and effectiveness. Bench data demonstrates this.

6. Performance Testing

Bench testing was conducted to determine device functionality and conformance to design input requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2 2001

HydroCision, Inc.
c/o Ms. Debbie Iampietro
QRC Consulting
7 Tiffany Trail
Hopkinton, Massachusetts 01748

Re: K011612
Trade/Device Name: HydroCision Debridement System
Regulation Number: 880.5475
Regulatory Class: II
Product Code: FQH
Dated: May 25, 2001
Received: May 25, 2001

Dear Ms. Iampietro:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K011612

Device Name HydroCision Debridement System

Indications For Use

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(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011612

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